

Federal agency for medicines and health products

Seminar LM4: Falsified Medicines Directive - Did they forget the hospital pharmacy?

Philippe De Buck 23-24 march 2017

22nd Congress of the European Association of Hospital Pharmacists (EAHP)



Disclosure

- Conflict of interest : nothing to disclose



Learning objectives

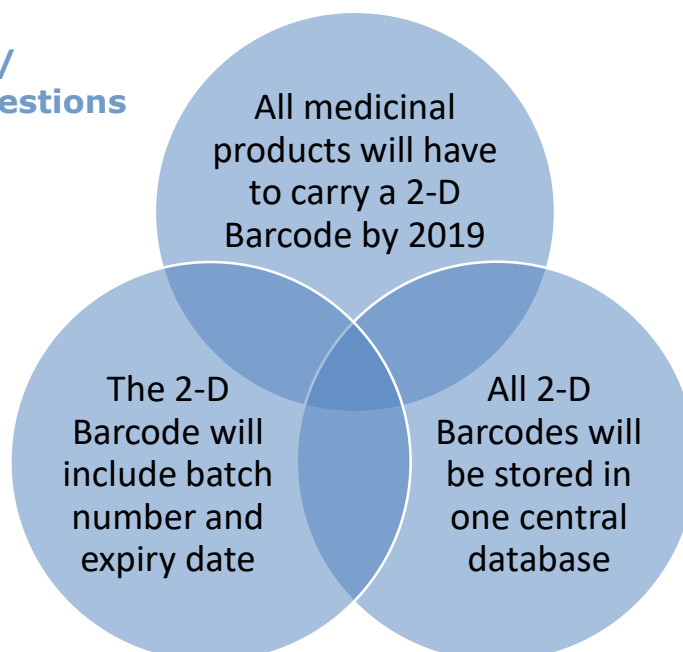
- understand the background, goal and flow of the required tracking system.
- understand the content of the barcode and the (inter)national repositories.
- estimate the impact for the hospital pharmacist when this system is implemented.
- evaluate cost/benefit of the system.



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Overview / control questions



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Falsified Medicines :



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Not as simple... : Definition FMD

Any medicinal product with a false representation of:

- (a) its identity, including its packaging and labelling, its name or its **composition** as regards any of the ingredients including excipients and the strength of those ingredients;
- (b) its **source**, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
- (c) its **history**, including the records and documents relating to the distribution channels used.



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...and not limited to lifestyle medicines

Lifestyle

- Erectile dysfunction
- Weight loss
- Alopecia
- ...

Mainstream

- Antibiotics
- Painkillers
- Antihistamines
-

Lifesaving

- Cancer treatment
- Antimalarial drugs
- HIV medicine
-



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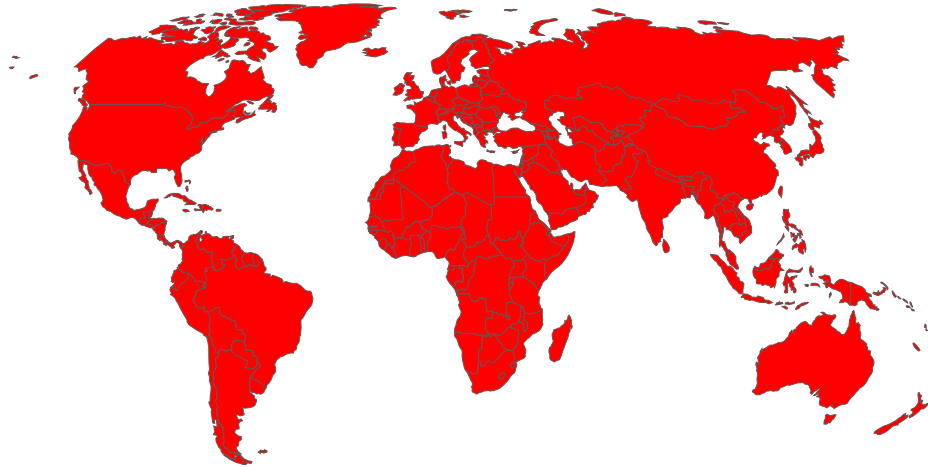
Geographic scope of the problem



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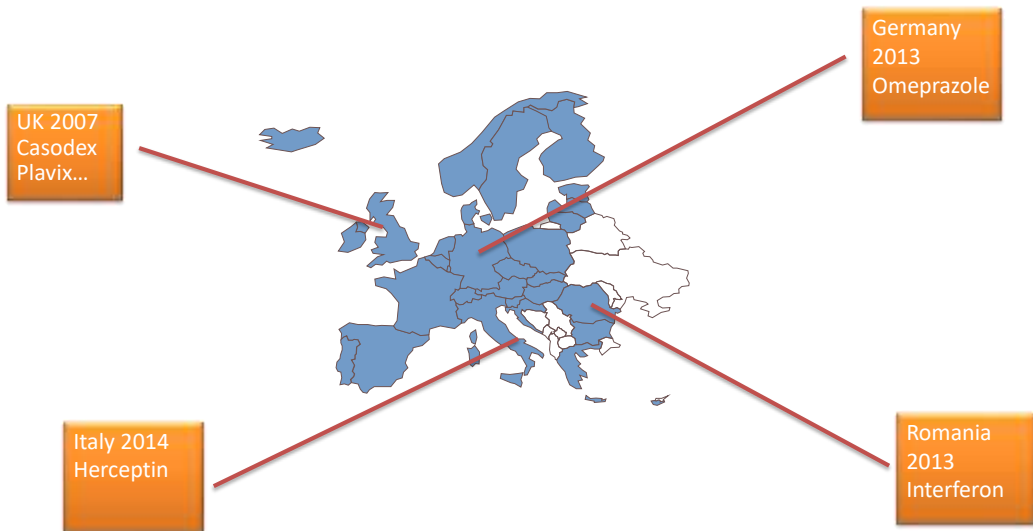
Geographic scope of the problem



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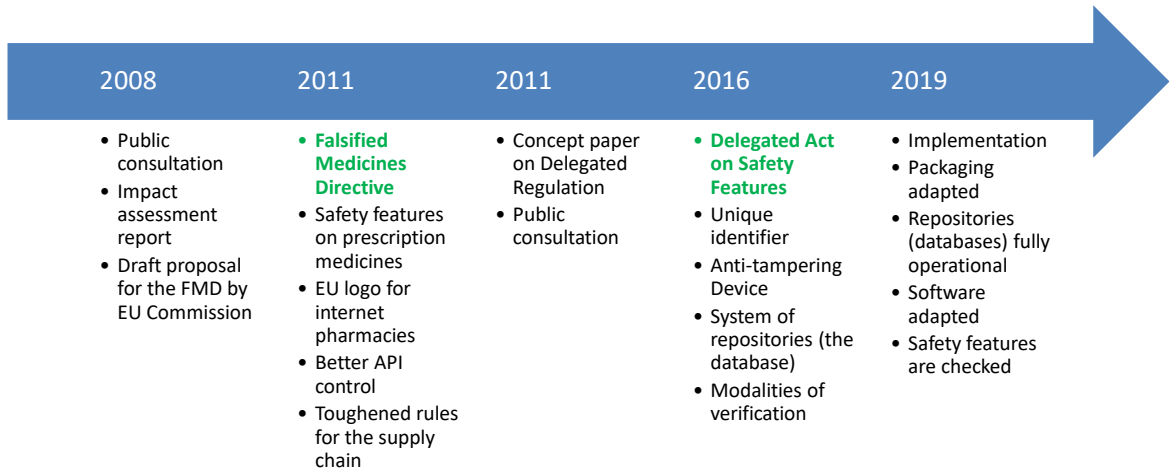
Geographic scope of the problem



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Action needed!



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In practice

Unique Identifier =

- Product Code
- Random Serial Number
- Batch number
- Expiry Date



PC : 012345000000001
 SN : AX12345S5R64556P351530135312
 EXP : 01012020
 BATCH : 18A21



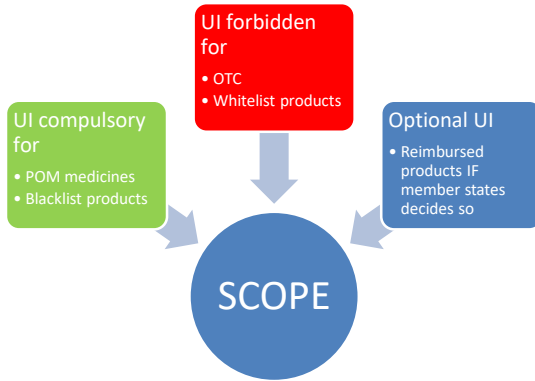
Encoding



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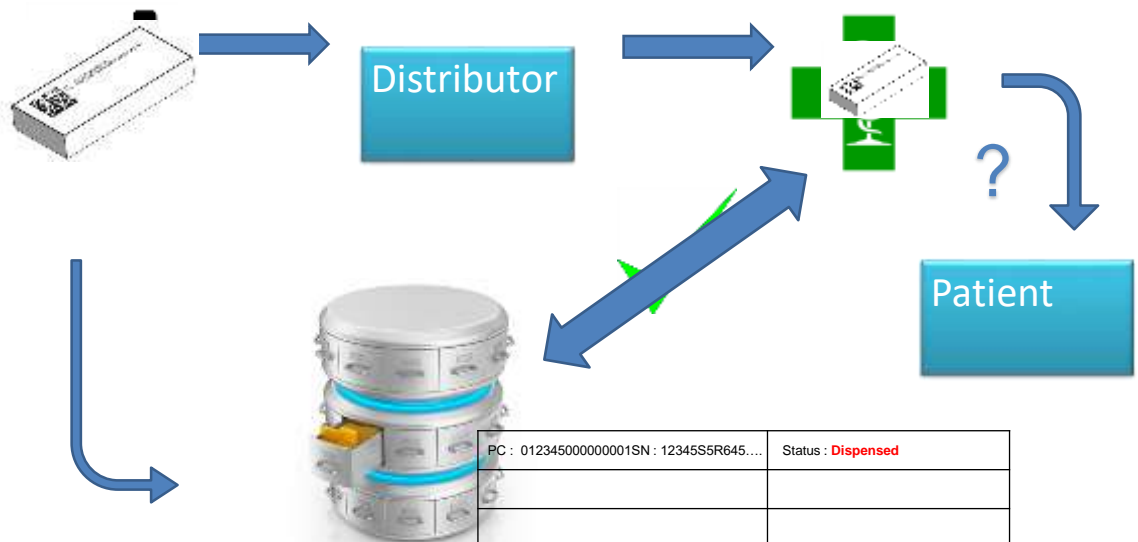
For which products?



| Whitelist |
|---|
| <ul style="list-style-type: none"> • Homeopathic medicines • Radionuclide generators • Gases • ATMP w/tissues or cells • Some contrast medias • Some IV solutions • |

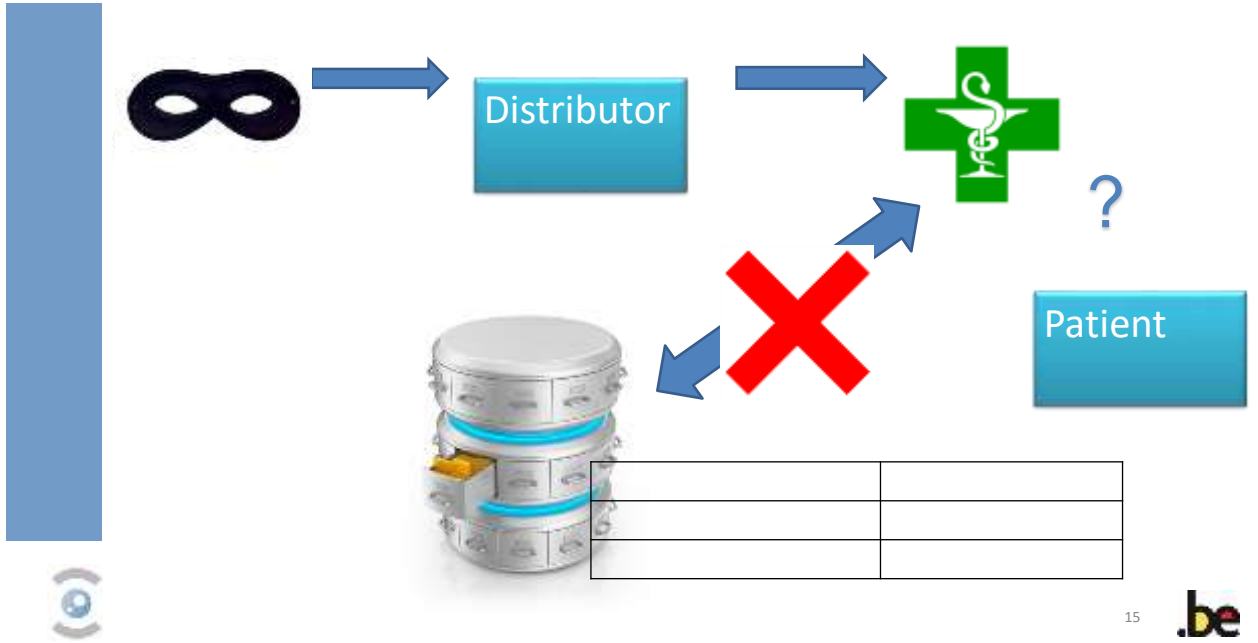
| Blacklist |
|--|
| <ul style="list-style-type: none"> • Omeprazole |

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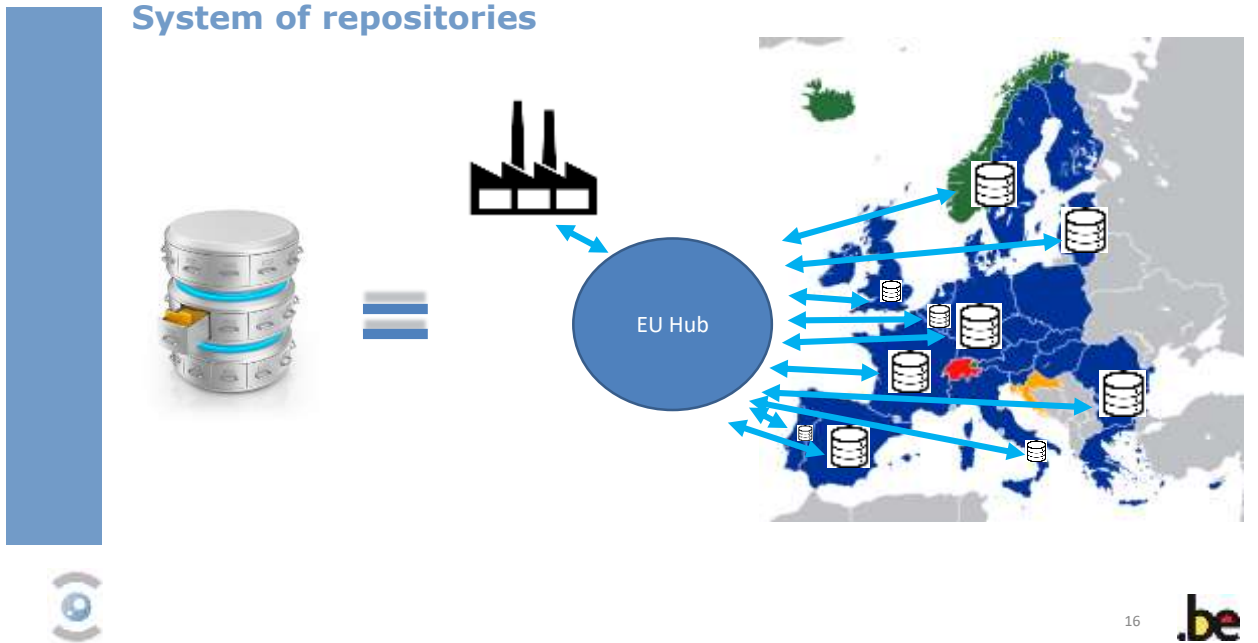


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System of repositories



Anti-tampering device

Same scope as UI

Can be extended by MS

Form : Left to MAH

- Sticker seal
- Shrink wrap
- Glue
- ...

To be checked by pharmacist!



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What is the risk/benefit for the hospital pharmacy



Risks

- Increased workload
- Checking can be at reception...
- ...but limits returns (10 days max.)
- Limited ROI
- No provision for bedside scanning

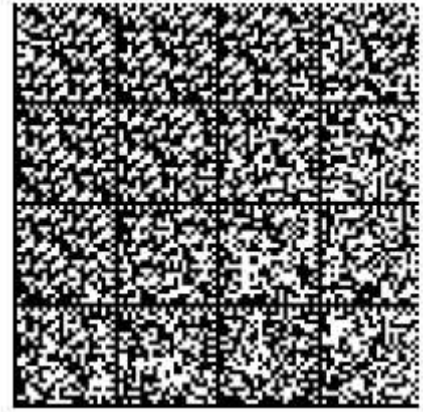


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Risk mitigation?

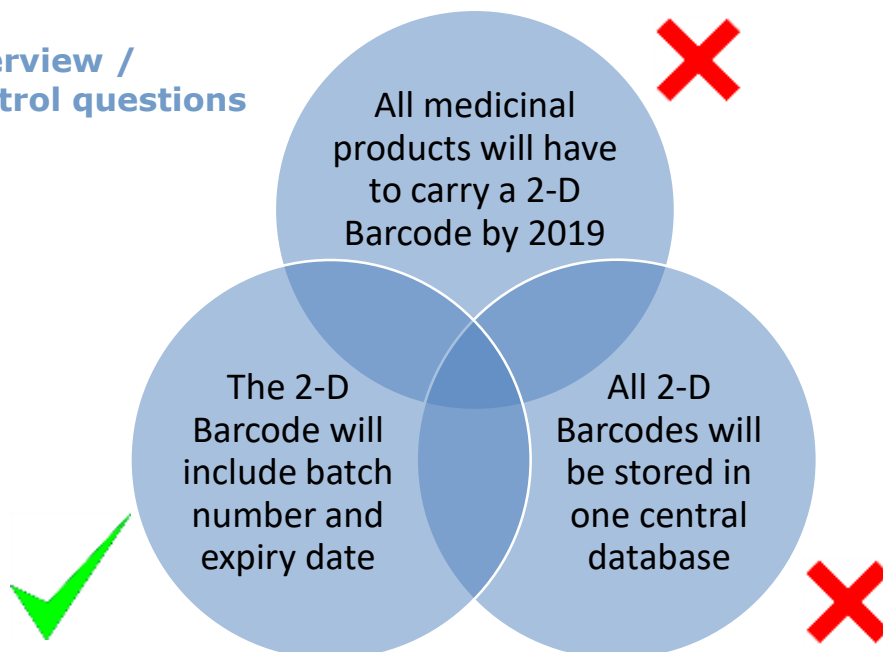
- Delegated Regulation
 - Exceptions on decommissioning
 - Aggregation : decommission “en masse”



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Overview / control questions



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Conclusions/take home message

9th February 2019 :

A lot of work for
industry...

...but also for the
hospital
pharmacist

- Adapt software to enable checking
- Adapt workflows and find resources
- Explore possibilities for optimization



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Contact

**Federal agency for medicines and health products -
famhp**

Place Victor Horta 40/40
1060 BRUXELLES

tel. + 32 2 528 40 00
fax + 32 2 528 40 01
e-mail welcome@fagg-afmps.be

www.afmps.be



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